DM-502 REVISION HISTORY

Date of Revision	Page(s)/Section(s) Revised	Revision Explanation
01AUG2011		
04APR2017		
31OCT2017	All	Cosmetic Only
26MAR2019	All	Minor corrections and updates.
3DEC2019	Section 9	Updated to include site initiated electronic records and signatures.

DM-502 STANDARD OPERATING PROCEDURE FOR MANAGEMENT OF ELECTRONIC RECORDS AND SIGNATURES

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) serves as a companion to DM-501, Standard Operating Procedure for Data Management. This investigative site follows DM-501 for general management of all clinical research data. We refer to this SOP for additional guidance concomitantly required when all or portions of the data that are required by an FDA predicate rule for a submission or inspection, are collected, managed, and/or transmitted electronically, or include the use of electronic signatures in required records.

2. SCOPE

This SOP applies to electronic data management for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics, and investigational device (IDE) regulations for medical devices, during all investigational phases of development. This SOP does not apply to computerized medical devices, diagnostic laboratory devices or analytical laboratory devices that are used during a clinical trial. Nor does it apply to paper records that are transmitted electronically.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812 Subpart E	Responsibilities of Investigators
21 CFR 812 Subpart G	Records and Reports
21 CFR 11	Electronic Records; Electronic Signatures

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
PM-302	Site-Sponsor/CRO Communications
PM-303	Regulatory Files and Subject Records
QA-601	Audits

5. ATTACHMENTS

N/A

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team and others involved in computerized system setup and use, and electronic data capture and management.

This includes the following:

- Sponsor
- Principal investigator

- Sub-investigator
- Research Director/Manager
- Research coordinator
- Support staff

7. DEFINITIONS

The following definitions from 21 CFR 11 and FDA guidance apply to this SOP.

Audit Trail: means a secure, computer generated, time-stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record.

Biometrics: means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.

Certified Copy: means a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original.

Computerized System: means computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial.

Digital Signature: means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

Direct Entry: means recording data where an electronic record is the original capture of the data. Examples are the keying by an individual of original observations into the system, or automatic recording by the system of the output of a balance that measures subject's body weight. In these cases, the electronic document is the source document.

Electronic Case Report Form (e-CRF): means an auditable electronic record designed to record information required by the clinical trial protocol to be reported to the sponsor on each trial subject.

Electronic Patient Diary: means an electronic record into which a subject participating in a clinical trial directly enters observations or directly responds to an evaluation checklist.

Electronic Record: means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Electronic Signature: means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Predicate Rule: means an FDA regulation that requires the submission to and/or inspection by FDA, of certain data and information relevant to FDA-regulated investigational and/or marketed products. Examples include clinical trial data to support a New Drug Application or device Premarket Approval application.

8. PROCESS OVERVIEW

A. System setup, training, security and maintenance
B. Collection of clinical research data

C. Transcription of the data to case report forms (CRFs), including remote data entry
D. Management of the data

9. PROCEDURES

A. SYSTEM SETUP, TRAINING, SECURITY AND MAINTENANCE

1. SPONSOR RESPONSIBILITIES

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Sponsor	For Sponsor required systems, retain primary responsibility for ensuring computerized systems used in clinical trial data management at this facility are in compliance with applicable regulations, as regards design and validation.
	Train all clinical research team members on the proper use of all sponsor-provided electronic systems used to capture study data (electronic patient diary, e-CRF), and on the relevant regulatory requirements.
	Train the research Director/Manager and/or research coordinator to conduct appropriate reviews of electronic data and audit trails at designated time periods.

2. RESEARCH SITE RESPONSIBILITIES

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Study Team	For Site required systems, retain primary responsibility for ensuring computerized systems used in clinical trial data management at this facility are in compliance with applicable regulations, as regards design and validation.
	Train all clinical research team members on the proper use of all sponsor-provided electronic systems used to capture study data (electronic patient diary, e-CRF), and on the relevant regulatory requirements.
	Train the research Director/Manager and/or research coordinator to conduct appropriate reviews of electronic data and audit trails at designated time periods.
	Work with sponsor to facilitate setup, implementation and maintenance of an FDA-compliant computerized system. ICR will require a letter from each site it is conducting trials with stating that the standards listed are maintained by the site as well.
	Work with sponsor to ensure that computerized systems used in clinical trials have a logoff or comparable security function after a designated period of inactivity.
	Assign unique and secure User ID/password combination for each clinical research team member who has access to the computerized system(s).
	Invalidate stolen, lost or otherwise compromised User ID/password combinations and replace with a new combination.
	Ensure that proper computer system function is routinely monitored.
	Ensure that sponsor-provided computerized systems are used only for the purposes for which they were intended and validated.

	Ensure that computerized systems are securely stored when not in use.
	Login using his or her unique User ID/password combination or other electronic signature when preparing to perform computer data entry or management functions.
	Do not divulge unique User ID/password combinations to anyone else for any purpose.
	Do not use anyone else's unique User ID/password combination or perform any required computer functions under anyone else's User ID/password combination.
	Log off when computer data entry/management activities are completed.

B. COLLECTION OF CLINICAL RESEARCH DATA

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Ensure protocol identifies at which steps a computerized system will be used.
	Maintain a record listing the hardware and software that will be used for each clinical trial.

C. TRANSCRIPTION OF THE DATA TO ESOURCE, EREGULATORY AND CASE REPORT FORMS (CRFS), INCLUDING REMOTE DATA ENTRY

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator Support staff	Ensure that sponsor-provided computerized systems and site computerized systems are used only for the purposes for which they were intended and validated.
	Ensure the audit trail documents all changes to electronic records (who, when, why) and that the original entries are not overwritten.
	Ensure that all annotations to electronic records are attributable as to who and when (date, time) the annotations are made.
	Enter all required data into the appropriate fields of e-CRFs
	Check and correct (or annotate) all data before transmitting the e-CRF to the sponsor.

D. MANAGEMENT OF THE DATA

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Ensure that an original or certified copy of all electronic source documents and audit trail records are retained on file.
	With respect to an FDA audit, treat electronic records as you would paper records.
	Ensure that changed CRFs and eCRFs also display all prior information.
	Retain audit trail records according to regulatory and sponsor requirements.